

expected extent for a medical condition and a pharmaceutical treatment, respectively; and the independent variables were types of medical condition or pharmaceutical treatment, types of information sources, frequency of past information search, health, extraversion, gender, and metropolitan statistical area. **RESULTS:** A total of 505 consumers yielded complete interviews, with a cooperation rate of 37.4%. On average, they were 57 years old, and 61% of them were female. Twenty percent of them had expectations of seeking information for a medical condition, and 14% for a pharmaceutical treatment. All regressions were significant ($p < 0.01$). Health and gender were significant predictors for expected likelihood, and health and extraversion were significant predictors for expected extent ($p < 0.05$). **CONCLUSIONS:** As perceived health status worsened, consumers were not only more likely to search for information, but also to a larger degree. Women were more likely to search for information, and those who were outgoing tended to perform information search to a larger degree.

PHP2

DIFFERENT STAKEHOLDER PERSPECTIVES ON PHARMACOGENOMIC TESTING

Patel H, Ursan I, Zueger P, Pickard AS
University of Illinois at Chicago, Chicago, IL, USA

OBJECTIVES: Although the potential benefits of pharmacogenomic (PG) testing may be readily evident, there are numerous concerns creating barriers to its implementation. The purpose of our study was to compare various stakeholder attitudes and concerns toward PG testing as identified from the literature. A sub-aim was to understand issues with PG testing identified by underrepresented groups. **METHODS:** Using specific keywords, we conducted a systematic literature search of electronic databases including PubMed, IPA, CINAHL, and EMBASE. Articles that evaluated the attitudes and beliefs about PG testing were included. Concerns identified in the studies were categorized into themes (ancillary information-related, clinical, economical, educational, ethical/legal, medical mistrust, and operational), and summarized according to stakeholder group (patients, general public, providers, payers and others). **RESULTS:** Of 1483 citations identified in the initial search, 38 studies that presented 41 perspectives met the inclusion criteria, employing methods of eliciting perceptions via surveys, focus groups and interviews. Overall, there were 15 studies focusing on providers, 9 on general public, 9 on patients, and 4 on payers, and 4 on other stakeholder perspectives. Studies of the general public most commonly identified issues related to medical mistrust ($n=5$), education ($n=5$) and operations ($n=5$). The most prevalent issues from the patient perspective included ethical/legal ($n=6$) and economical ($n=5$). Clinical ($n=11$) and educational ($n=11$) issues related to PG testing were recognized as frequent among the providers. Among the payer perspective, operational ($n=4$) and clinical ($n=3$) issues were prominent. In the underrepresented groups, concerns of medical mistrust and economical issues were notably higher compared to other groups. **CONCLUSIONS:** While the number of studies, assessing attitudes and concerns of various stakeholders, has increased over the last five years, the fundamental issues remain unchanged. Improved understanding of such issues may help strengthen the uptake of pharmacogenomic testing in clinical practice and lead to better health outcomes.

PHP3

PUBLIC ENGAGEMENT MECHANISMS IN HEALTH TECHNOLOGY ASSESSMENT (HTA): AN EARLY ASSESSMENT OF CANADA'S NATIONAL HTA PUBLIC ENGAGEMENT INITIATIVES

Tran JB

Double Helix Consulting, London, UK

OBJECTIVES: To address questions about the importance of public (patients, patient groups, etc) engagement in HTA processes with the objective to - 1) explore ideas regarding the use of public engagement in decision making processes (specifically coverage decisions), and 2) contextualise some of the main arguments found by assessing the Canadian Agency for Drugs and Technologies in Health's (CADTH) current public engagement mechanisms for its Common Drug Review (CDR). **METHODS:** A literature search was performed to identify key theoretical arguments for and against public engagement in HTA processes. The search was mainly focused on sources from Canada and the UK. A review of CADTH's website was conducted for technology appraisals completed by the CDR process since the start of its public engagement initiatives (to mid-August 2012). **RESULTS:** Key arguments for public engagement in decision making include: transparency, accountability, equity, and creating a patient-centric health system. With the CDR, the percentage of appraisals conducted for coverage decisions that included public (patient group) input was 48%. The lack of engagement from patient groups on half of the appraisals highlights some of the key challenges of public engagement (e.g., lack of awareness, lack of budget). Furthermore, the documents reviewed showed that some indications received more responses than others (e.g., epilepsy, schizophrenia). This may potentially result in some underfunded patient groups feeling disempowered, which is a risk of engagement. **CONCLUSIONS:** The findings of the study support initiatives that encourage the engagement of the public so that decision makers can better incorporate the values held by citizens. However, the relative value of doing so will vary. To ensure that public engagement in HTA is appropriate and fair, Canada and other jurisdictions must have political will, dedicated resources, and the motivation to facilitate educational activities that support active engagement from all types of public.

PHP4

PRICE ELASTICITY AND MEDICATION USE: COST-SHARING IN MULTIPLE CHRONIC CONDITIONS

Gatwood J¹, Gibson TB², Chernew M³, Farr A⁴, Vogtmann E⁵, Fendrick M⁶

¹University of Michigan, Ann Arbor, MI, USA, ²Truven Health Analytics, Ann Arbor, MI, USA,

³Harvard Medical School, Boston, MA, USA, ⁴Truven Health Analytics, Washington, DC, USA,

⁵University of Alabama at Birmingham, Birmingham, AL, USA, ⁶University of Michigan Center

for Value-Based Insurance Design, Ann Arbor, MI, USA

OBJECTIVES: To examine the impact of cost-sharing on the demand for medication across several classes of prescription medications indicated to treat chronic conditions. **METHODS:** Data from the 2005-2009 MarketScan Commercial Claims and Encounters databases were used to evaluate prescription fills across 10 categories of medications. The date of first fill served as the index date for each subject and patterns of use were analyzed for at least seven continuous calendar quarters within the study window. Cost sharing, expressed as a price index for each medication class, was the main explanatory variable to examine price elasticity of demand. This index was based on the average cost-sharing amount per prescription and was weighted using the national proportion of generic and brand medication within each drug category. Negative binomial generalized estimating equations models were constructed to examine medication fills; standard demographic variables were used to control for confounding. **RESULTS:** Prescription fills per enrollee ranged from 0.01 (smoking deterrents) to 0.23 (Statins) and the average spending for medications showed considerable variability: those taking thyroid hormone reported an average expenditure of \$31.29 while those on antiplatelets had an average expenditure of \$330.38. Additionally, the share of generic drug use within each category ranged from 4.7% (smoking deterrents) to 88.4% (NSAIDs/Opioids). Estimates from the negative binomial models revealed that the price elasticity of demand ranged from -0.015 to -0.157 within the 10 categories of medications ($p < 0.05$ for 9 of 10 categories). Demand for smoking deterrents proved to be the most price elastic of drug categories (-0.157), while NSAIDs/Opioids were observed to be relatively price inelastic (-0.015). **CONCLUSIONS:** The price elasticity of demand varied considerably by medication category, suggesting that the influence of cost-sharing on medication use may be related to characteristics inherent to each medication class or underlying condition.

PHP5

AN ANALYSIS OF THE RELATIONSHIP BETWEEN GROWTH IN PATIENT COST SHARING DUE TO BENEFIT DESIGN SHIFTS AND DIAGNOSTIC PRICING AND SPENDING

Abraham J, Garfield S, Sulham K

GfK Bridgehead, Wayland, MA, USA

OBJECTIVES: Consumers are shouldering an increasing percentage of health care expenditures through cost-sharing mechanisms embedded in benefit design structures. As a result, many patients are paying out-of-pocket for some or all of the costs associated with diagnostic testing. Traditionally, diagnostic companies have focused on demonstrating value to payers with the goal of achieving adequate pricing and reimbursement. Though this approach will remain necessary, patients are an increasingly critical stakeholder in determining whether a diagnostic's value supports the resulting out-of-pocket costs. This study examined how out-of-pocket expenditures by individuals, national health expenditures (NHE) on diagnostics, and the price index for diagnostics grew between 2005 and 2011. **METHODS:** A systematic review of published literature related to health care expenditure, health insurance coverage, diagnostic pricing, and benefit design was performed. In follow-up, data from the Centers for Disease Control and Prevention, Bureau of Labor Statistics, Employer Benefits Health Survey, and diagnostic industry reports were reviewed to examine growth rates over the study period. Basic statistical methods were employed to determine how average annual growth rates within each segment relate to other variables being considered. **RESULTS:** The proportion of individuals in America with high-deductible health plans has increased 475% in the last six years. This correlates to over 25 million Americans responsible for at least \$2000 in deductible costs in addition to coinsurance and co-pays. During this period, pricing of diagnostics only rose at an average annual rate of 1.0%. Overall spending on health care increased while diagnostics expenditure remained consistent at 6% of NHE. **CONCLUSIONS:** As health care continues to transform, the demand for high quality diagnostics will continue to grow. However, the increasing financial burden borne by individuals will lead to increased price sensitivity. Novel technologies will need to demonstrate value and clinical utility not only to payers, but to patients, to achieve pricing and reimbursement.

PHP6

RACIAL DISPARITY IN DURATION OF PATIENTS' VISITS TO THE EMERGENCY DEPARTMENT: TEACHING VERSUS NON-TEACHING HOSPITALS

Wong H, Karaca Z

Agency for Healthcare Research and Quality (AHRQ), Rockville, MD, USA

OBJECTIVES: Racial disparity in duration of patients' visits to emergency departments (EDs) have not been well documented. This study explores the racial disparity in duration of routine visits to EDs at teaching and non-teaching hospitals. **METHODS:** Retrospective data analyses and multivariate regression analyses were performed to investigate the racial disparity in duration of routine ED visits at teaching and non-teaching hospitals. Duration for each visit was computed by taking the difference between admission and discharge times. The Healthcare Cost and Utilization Project (HCUP) State Emergency Department Databases (SEDD) were used in the analyses. The data include 4.3 million routine ED visits encountered in Arizona, Massachusetts, and Utah during 2008. SEDD provide detailed diagnoses, procedures, total charges, patient demographics, and admission and discharge time for each visit. We linked SEDD files with American Hospital Association Annual Survey Database, Trauma Information Exchange Program Database and Area Resource File to obtain hospital and area level characteristics. **RESULTS:** The mean duration for a routine ED visit was 238

minutes at teaching hospitals and 175 minutes at non-teaching hospitals. There were significant variations in duration of routine ED visits across race groups at teaching and non-teaching hospitals. The risk-adjusted results show that the mean duration of routine ED visits for black/African American and Asian patients when compared to visits for white patients was shorter by 10.0 and 3.4 percent, respectively, at teaching hospitals; and longer by 3.6 and 13.8 percent, respectively, at non-teaching hospitals. Hispanic patients experienced 8.7 percent longer ED stays when compared to white patients at non-teaching hospitals. **CONCLUSIONS:** There is significant racial disparity in the duration of routine ED visits, especially in non-teaching hospitals where non-white patients experience longer ED stays compared to white patients. The variation in duration of routine ED visits at teaching hospitals when compared to non-teaching hospitals was smaller across race groups.

HEALTH CARE USE & POLICY STUDIES – Diagnosis Related Group

PHP7

DRG SYSTEM IN ITALY: EVALUATION OF DIFFERENT REIMBURSEMENTS FOR SURGICAL PROCEDURES AT NATIONAL, REGIONAL AND HOSPITAL LEVEL

Velleca M¹, Petrarca G², Perrone F¹

¹Johnson & Johnson Medical, Pomezia (RM), Italy, ²Centro Studi Assobiomedica, Milano, Italy

OBJECTIVES: The Italian National Health Service (Servizio Sanitario Nazionale-SSN) is structured on two levels: the national and regional level. The national government defines the benefits package (essential levels of care, *livelli essenziali di assistenza-LEA*) to which citizens are constitutionally entitled and which each Regional Health Service (Servizio Sanitario Regionale-SSR) is responsible for. Since 1997 the regions have been fully autonomous in organizing and managing their SSR, including the definition of DRG tariffs for hospital admissions. The aim of this study is compare the regional differences among tariffs for the main surgical DRGs of each Major Diagnostic Category (MDC). **METHODS:** In order to identify the surgical DRGs with the highest volumes for each MDC, we used the dataset of admissions registered in 2010 by all hospitals (DRG version 24 ICD9-CM), published by the Italian Department of Health (Ministero della Salute), and we analyzed the variability among tariffs by calculating their average and standard deviations (the extra-reimbursement has not been considered). **RESULTS:** Average tariffs were calculated starting from the standard regional tariff for each DRG. Comparing the first 10 DRGs, we identified a variation in the average tariff which rose from -1.8% to +22.6% and a standard deviation with a minimum of 425€ and a maximum of 1443€. Further complexity is given by the intra-regional variation by type of hospital, where we observed a variation inside the same region of 82% for the same DRG. **CONCLUSIONS:** The SSN is characterized by a high variability of regional DRG tariffs, also inside the regions. Moreover in Italy there is not a defined procedure to update the classification of DRGs and the related tariffs. Therefore there is a need to establish a systematic periodical review, which should involve all the different stakeholders of SSN, and to share data updated with them about the volume of admissions.

PHP8

SWITCHING THE PERFORMANCE VOLUME LIMIT (PVL) TO DEGRESSIVE FINANCING METHOD IN THE HUNGARIAN DRG-BASED HOSPITAL REIMBURSEMENT BETWEEN 2009-2012

Endrei D, Decsi T, Bódis J, Zemplényi A, Ágoston I, Molics B, Boncz I

University of Pécs, Pécs, Hungary

OBJECTIVES: The aim of our study was to investigate the financial effects of switching from the so-called performance volume limit (PVL) to degressive financing method in the Hungarian DRG-based hospital financing. **METHODS:** The data in our analysis were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency. We examined mainly the period between 2009 and 2012. The difference in hospital reimbursement between the preannounced DRG reimbursement rate and degressive cap (upper ceiling) was calculated both on national level and in the case of the Clinical Center of the University of Pécs. **RESULTS:** The ratio of partially paid [based on preannounced performance base-fee (PPBF) or performance volume limit (PVL) financing method] active inpatient cost-weights to total cost-weights varied extremely between 2009-2012. In the case of PPBF financing in 2009, 25-30% of the total national performance fell under floating fee structure, resulting in a monthly change in the monetary (Hungarian Forint, HUF) value of a DRG cost-weight. In the case of degressive PVL from 2011 onwards, one to seven percent of the national performance fell in the degressive zone, with a prefixed value of HUF 45,000/cost-weights. For the Clinical Centre of the University of Pécs, this partial reimbursement resulted in a large financial deficit in 2009, when PPBF was applied. In 2010 and 2011, the deficit of the University of Pécs lessened to some extent compared to 2009; however, it was still rather high (HUF 1.46 and HUF 1.3 billion, respectively). Due to partial health insurance reimbursement, the University of Pécs realized HUF 8.1 billion revenue losses between 2004 and 2012. **CONCLUSIONS:** Application of preannounced performance base-fee rendered institutional financing nearly incalculable. Renewed introduction of degressive performance volume limit in 2011 made institutional financing more calculable; however, it failed to entirely stop source withdrawal.

HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP9

TRENDS IN USE OF HEALTH ECONOMIC EVIDENCE FOR DEVELOPING CLINICAL GUIDELINES

Aggarwal S, Topaloglu H, Kumar S, Segal J, McGrane M
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: The recent reforms and policy changes have increased the cost pressures on all health care stakeholders, including clinical experts. In the past, clinical guidelines were developed independent of cost or economic considerations. However, increasingly, more clinical guidelines are mentioning cost concerns and referring to economic data in new recommendations. The objective of this study was to analyze trends in the use of health economic information for developing clinical guidelines. **METHODS:** To understand trends in use of health economic information we conducted targeted search for clinical guidelines, expert recommendations, and consensus statements with specific mention of “cost” or “economic” or related terms. A systematic literature search was undertaken for the databases Pubmed, Google Scholar and Cochrane. The guidelines published between 2003-2012 were included. For guidelines which met the search criteria, data was collected for the name of the authors, indication, year of publication, country/region, and context of use of cost/economic evidence. **RESULTS:** Sixteen clinical guidelines published between 2003-2012 met the inclusion criteria for specific mention of cost/economic evidence. More than 50% of these guidelines were published between 2006-2012. For indication, 3 out of 16 guidelines were for diabetes, while the rest were for different indications. In these 16 guidelines “cost effectiveness” was mentioned 14 times, either referencing cost-effectiveness data or to mention the importance of such data for selecting treatment options. The guidelines commonly cite high cost of disease or high economic burden as one of the considerations for developing new recommendations (11 out of 16). Another term that was commonly used by these guidelines was “cost-benefit,” which was mentioned 5 times in these guidelines. Notably, QALY was rarely mentioned (1 out of 16 times) in these guidelines. **CONCLUSIONS:** This analysis suggests that some clinical experts groups are increasingly showing willingness to use and incorporate health economic information for developing new recommendations.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP10

ANALYSIS OF THE WAXMAN-HATCH ACT PHARMACEUTICAL PATENT EXTENSIONS (1984-2012)

Bin Sawad AH¹, Alshahrani AM¹, Seoane-Vazquez E², Rodriguez-Monguio R³

¹Massachusetts College of Pharmacy and Health Sciences University, Boston, MA, USA, ²MCPHS University, Boston, MA, USA, ³University of Massachusetts, Amherst, MA, USA

OBJECTIVES: The Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman- Hatch Act - WHA) established a patent extension system that allows sponsors of new drugs (NDAs) and biologic applications (BLAs) approved by Food and Drug Administration (FDA) to recover part of the patent time dedicated to clinical trials and to the FDA drug review process. The maximum extension is 5 years and the effective patent life from approval to patent expiration cannot exceed 14 years. We assessed the characteristic of drugs and biologics that had a patent extension in the period 1984-2012 and examined the patent life timeline from clinical trials to regulatory review, and from marketing authorization to patent expiration (i.e. effective patent life). **METHODS:** Data were derived from the FDA, the US Patent and Trademark Office, and the US Federal Register. Descriptive analyses were performed. T-test was used to assess differences in averages. Significant level was set at 0.05. **RESULTS:** The USPTO listed 499 pharmaceuticals with patent extensions in the study period; 453 NDAs (90.8%), 38 BLAs (7.6%), and 9 vaccines (1.8%). Drug regulatory and patent information was available for 323 pharmaceuticals (287 NDA, 32 BLA and 4 vaccines). The average±stdev patent extension was 2.7±1.4 years (median=2.2 years; 95% CI=2.62,8). The extension was longer for vaccines (3.7±1.3 years) than for NDAs (2.7±1.4 years) and BLAs (2.4±1.5 years). The average clinical trials time was 5.9±3.1 years, being similar for NDAs, BLAs and vaccines. The average FDA review time was 1.7±1.3 years (higher for vaccines 2.6±2.5 years). The average length of the effective patent life was 8.7±7.0 years without patent extensions and 11.7±6.8 years after the extensions. **CONCLUSIONS:** A large number of pharmaceuticals were granted patent extensions in the US. The WHA significantly increased the effective patent life of pharmaceuticals.

PHP11

PRELIMINARY STUDY ON DEVELOPMENT OF BUDGET IMPACT ANALYSIS GUIDELINES IN KOREA: THE COMPARISON OF GUIDELINES ON BUDGET IMPACT ANALYSIS FOR HEALTH TECHNOLOGIES

Jeon HR, Lim MK, Yu SY

Health Insurance Review & Assessment Service, Seoul, South Korea

OBJECTIVES: A budget impact analysis(BIA) is a useful tool for a health care decision maker in estimating the financial impact of the new technology. In Korea, the content and presentation of results of the BIA have been proposed but detailed guidance on methods for BIA are not yet available. To evaluate the international landscape of BIA guidance, we compared guidelines of BIA outside of Korea. **METHODS:** A literature review was performed. Research for guidelines was based on data published in latest official papers or reports from ISPOR and national institutes in Canada, Ireland, and Poland. **RESULTS:** In all guidelines, the recommended perspective was that of public purchaser. A time horizon of 2-5 years was considered to be desirable. It was stated that data on a technology and its use should be included in BIA, which is helpful for decision makers. Published guidelines provided a similar description of target population, but it was different whether or not off-label usage of drugs was included in assumption of population size. The approaches to measurement and evaluation of costs varied in different regions. The costing included direct costs associated with the technology in four guidelines but items of other costs were specified